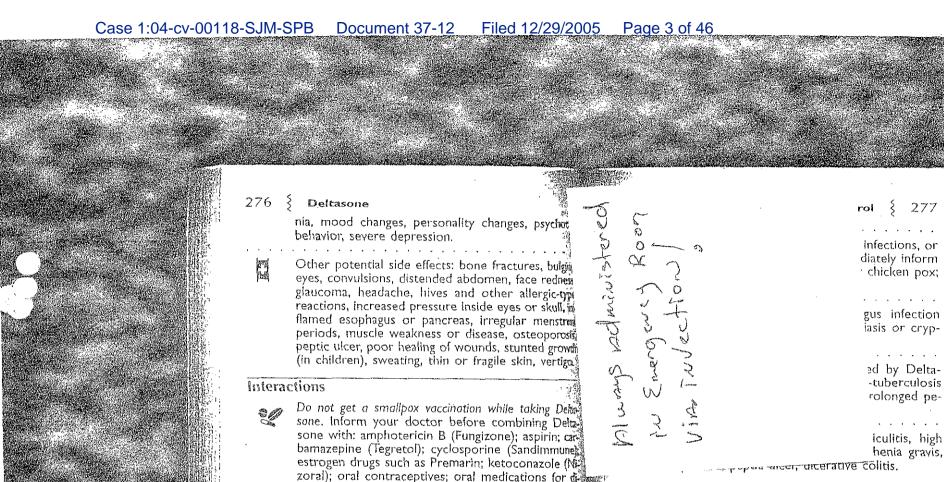
## Appendix L

## Misc. Narcotic Painkillers



abetes such as Insulin; phenytoin (Dilantin); potent

If pregnant or planning to become pregnant, inform

your doctor immediately. Not known if Deltasone

Not generally prescribed for children, if prescribed be aware that Deltasone may stunt growth if taken

Do not take if sensitive to or had an allergic reaction to

Use with extreme caution if you have an eye infec-

No known food/other substance interactions.

diuretics such as Lasix; rifampin (Rifadin).

No special precautions apply to seniors,

**Special Cautions** 

appears in breast milk.

for a prolonged period.

tion caused by herpes simplex.

Generic name: Meperidine hydrochloride
Other brand names: Pethadol, Pheperidine
Hydrochloride

Demend is a margoric analgesic it works by altering the response to painful stimuli.

#### B QUICK FACTS

Purpos	e
$\mathbf{R}$	<u> Used to treat moderate to severe pair</u>
. /	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1

#### Dosage

Take exactly as prescribed. If using syrup form, take with a half glass of water.

Usual dult does 50 to 100 millionens e 3 or 4 hours. Seniors: doctor may reduce dosage.



278 Demerol

Demerol }

270

Usual child dose: 0.5 to 0.8 milligram per pound of body weight, every 3 or 4 hours.

·**'** 

Missed dose: take as soon as possible, unless almost time for next dose. In that case, do not take missed dose; go back to regular schedule. Do not double doses.

#### Side Effects

Overdose symptoms: bluish discoloration of the skin cold and clammy skin, coma or extreme sleepiness limp and/or weak muscles, low blood pressure, slow heartbeat, troubled or slowed breathing. Severe or dose may result in breathing stoppage, heart attack a death. If you suspect an overdose, immediately see medical attention.



More common side effects: dizaness fight header ness, nausea, sedation, sweating, vomiting.



Less common or rare side effects: agitation, consipation, difficulty urinating, disorientation, dry mouth, fainting, fast heartbeat, feeling of elation or depression, flushing of the face, hallucinations, headache, hives, impairment of physical performance, itching, low blood pressure, mental sluggishness or clouding, palpitations, rashes, restlessness, severe convulsions, slow heartbeat, tremors, troubled and slowed breathing, uncoordinated muscle movements, visual disturbances, weakness.

#### Interactions



Do not take with MAO inhibitors such as Nardil or Parnate. Inform your doctor before combining Demeral with: antidepressants such as Elavil and Tofranil antihistamines such as Benadryl; cimetidine (Tagamet); major tranquilizers such as Mellaril and Thorazine, other narcotte painfallers such as Percocet and Tylenol with Codeine; phenytoin (Dilantin); sedatives such as Halcion and Restoril; tranquilizers such a Xumo and rangell.

Special Cautions

If pregnant or planning to become pregnant, inform your doctor immediately. Demerol appears in breast milk; could affect a nursing infant.

Do not drink alcohol while taking Demerol; slows brain



Doctor may reduce dosage for seniors.

activity and intensifies the effects of alcohol.



Follow doctor's instructions carefully for children.



May impair, your ability to drive a car or operate machinery. Play also cause dryzmess or hight-headed hess. Do not toke barr in any activity that requires alertcess.

Should not take if sensitive to, or had an allergic reaction to Demerol or other narcotic painkillers.

Monitor for mental and physical tolerance if you take Demerol on an ongoing basis, or if you have had a drug abuse problem.

Use with extreme caution if you have a severe asthma attack, if you have recurring lung disease, if unable to inhale or exhale extra air when needed.

Use with caution if you have: Addison's disease, an enlarged prostate, convulsions, head injury, irregular heartbeat, severe abdominal condition, severe liver or kidney disorder, underactive thyroid gland, or urethral stricture.

Notify your doctor that you are taking Demerol before having surgery.

## Appendix M

## Antianxiety-Agents Profile of the Substance

#### HISTORICAL PERSPECTIVES\*

Historically, reaction to and treatment of the mentally ill ranged from benign involvement to intervention some would consider inhumane. Mentally ill individuals were feared because of common beliefs associating them with demons or the supernatural. They were looked upon as loathsome and were often mistreated.

Beginning in the late 18th century, a type of "moral reform" in the treatment of the mentally ill began to occur. This resulted in the establishment of community and state hospitals concerned with the needs of the mentally ill. Considered a breakthrough in the humanization of care, these institutions, however well-intentioned, fostered the concept of custodial care. Patients were assured the provision of food and shelter but with little or no hope of change for the future. As they became increasingly dependent on the institution to fill their needs, the likelihood of their return to the family or community diminished.

The early part of the 20th century saw the advent of the somatic therapies in a sill

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Nurses must understand the legal implications

\*From Townsend, M. C. (1990), pp 1-2.

associated with administration of psychotropic medications. Laws differ from state to state, but most adhere to the patient's right to refuse treatment. Exceptions exist in emergency situations when it has been determined that patients are likely to harm themselves or others.

#### ANTIANXIETY AGENTS

#### Indications

Antianxiety drugs are also called *anxiolytics* and *minor tranquilizers*. They are used in the treatment of anxiety disorders, anxiety symptoms, acute alcohol withdrawal, skeletal muscle spasms, convulsive disorders, status epilepticus, preoperative sedation, and relief of anxiety. Their use and efficacy for periods greater than 4 months have not been evaluated.

#### Action

Antianxiety drugs depress subcortical levels of the central nervous system (CNS), particularly the limbic system and reticular formation. They may potentiate the effects of the powerful inhibitory neurotransmitter gamma-aminobutyric acid in the brain, thereby producing a calmative effect. All levels of CNS depression can be effected, from mild sedation to hypnosis to coma.

EXCEPTION: Buspirone (BuSpar) does not depress the CNS. Its action is unknown, but the drug is believed to produce the desired effects through interactions with serotonin, dopamine, and other neurotransmitter receptors.

#### Contraindications/Precautions

Antianxiety drugs are contraindicated in individuals with hypersensitivity to any of the drugs within the classification (i.e., anxiolytics) or group (e.g., benzodiazepines). They should not be taken in combination with other CNS depressants and are contraindicated in pregnancy and lactation, narrow-angle glaucoma, shock, and coma.

Caution should be taken in administering these drugs to elderly or debilitated patients and patients with hepatic or renal dysfunction. (The dosage will generally have to be decreased.) Caution is also required with individuals who have a history of drug

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abuse/addiction and with individuals who are depressed or suicidal. In depressed patients, CNS depressants can exacerbate symptoms.

#### Examples of Commonly Used Antianxiety Agents (by Chemical Group) and the Daily Adult Dosage Rance

E Chemical Group	Generic (Trade) Nam <b>e</b>	Daily Dosage Range
Antibus ammes	nvorovezne finistani kanevi	1 1001 100 1511
Benzodiazepines	alprazolam (Xanax)	0.75 – 4 mg
	chlordiazepoxide (Librium)	15-100 mg
	clorazepate (Tranxene)	15-60 mg
	diazepam (Valium)	5-40 mg
	halazepam (Paxipam)-	60-160 mg
	lorazepam (Ativan)	2-9 mg
	oxazepam (Serax)	30-120 mg
	prazepam (Centrax)	10-60 mg
Metathiazanones	chiormezanone (Trancopal)	100-800 mg
Propanediols	meprobamate (Equanil, Miltown)	200-2400 mg
Miscellaneous	buspirone (BuSpar)	15-60 mg

#### Side Effects and Kursing Implications

Nursing implications are designated by an asterisk [\*].

- Drowsitiess, confusion, lethergy (in Mon. side effects)
  - Instruct patient not to drive or operate dangerous: machinery, while taking medication.
- Tolerance; physical and psychological dependence (does not apply to buspirone)
  - \* Instruct patient on long-term therapy not to quit taking the drug abruptly. Abrupt withdrawal can be life threatening. Symptoms include depression, insomnia. increased anxiety, abdominal and muscle cramps, tremors, vomiting, sweating, convulsions, and delirium.

3. Potentiates the effects of other GNS depressants

Instructional entirection drink alcohologiaka other medications that depress the CNS while taking this medication.

#### 4. May aggravate symptoms in depressed persons

- \* Assess mood daily.
- \* Take necessary precautions for potential suicide.

#### 5. Orthostatic hypotension

- \* Monitor vital signs.
- \* Instruct patient to arise slowly from a lying or sitting position.

#### 6. Paradoxical excitement

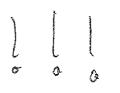
- . Withhold drug and notify physician.
- 7. Dry mouth
  - Have patient take frequent sips of water, suck on ice chips or hard candy, or chewsugarless gum.

#### 8. Nausea and vomiting

- \* May take drug with food or milk.
- 9. Blood dyscrasias
  - \* Symptoms of sore throat, fever, malaise, easy bruising, or unusual bleeding should be reported to the physician immediately.

#### 10. Delayed onset (buspirone only)

\* Ensure that patient understands there is a lag time of 7 to 10 days between onset of therapy with buspirone and subsiding of anxiety symptoms. Patient should constitute the street of the street.



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oduce apres-

#### 164 THERAPEUTIC APPROACHES IN PSYCHIATRIC CARE

- sion, insomnia, anxiety, abdominal and muscle cramps, tremors, vomiting, sweating, convulsions, and delirium.
- \* (With buspirone only): Be aware of lag time between start of therapy and subsiding of symptoms. Relief is usually evident within 7 to 10 days. Be sure to take medication regularly, as ordered, so that it has sufficient time to take affect
- Not consume other CNS depressants, including alcohol.
- \* Not take nonprescription medication without approval from physician.
- \* Rise slowly from sitting or lying position to prevent sudden drop in blood pressure.
- \* Report symptoms of sore throat, fever, malaise, easy bruising, unusual bleeding, or motor restlessness to physician immediately.
- \* Be aware of risks of taking this drug during pregnancy. (Congenital malformations have been associated with use during first trimester.) Notify physician of desirability to discontinue drug if pregnancy is suspected or planned.
- Be aware of possible side effects. Refer to written materials furnished by health-care providers regarding correct method of self-administration.
- \* Carry card or piece of paper at all times stating names of medications being taken.

#### ANTIDEPRESSANTS

#### Indications

Antidepressant medications are used in the treatment of dysthymic disorder; major depression with melancholia or psychotic symptoms: depression associated with organic disease, alcoholism, schizophrenia, or mental retardation; depressive phase of bipolar disorder; and depression accompanied by anxiety. These drugs elevate mood and alleviate other symptoms associated with moderate-to-severe depression.

#### Action

These drugs ultimately work to increase the concentration of norepinephrine and serotonin in the body. This is accomplished in the brain by blocking

the reuptake of these chemicals by the neurons (unicyclics, bicyclics, tricyclics, tetracyclics, and others). It also occurs when an enzyme, monoamine oxidase (MAO), that is known to inactivate norepinephrine and serotonin is inhibited at various sites in the body (MAO inhibitors).

#### Contraindications/Precautions

Antidepressant drugs are contraindicated in individuals with hypersensitivity. They are also contraindicated in the acute recovery phase following myocardial infarction and in individuals with angle-closure glaucoma.

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Caution should be taken in administering these drugs to elderly or debilitated patients and patients with hepatic, renal, or cardiac insufficiency. (The dosage will generally have to be decreased.) Caution is also required with psychotic patients, with patients who have benign prostatic hypertrophy, and with individuals who have a history of seizures (may decrease seizure threshold).

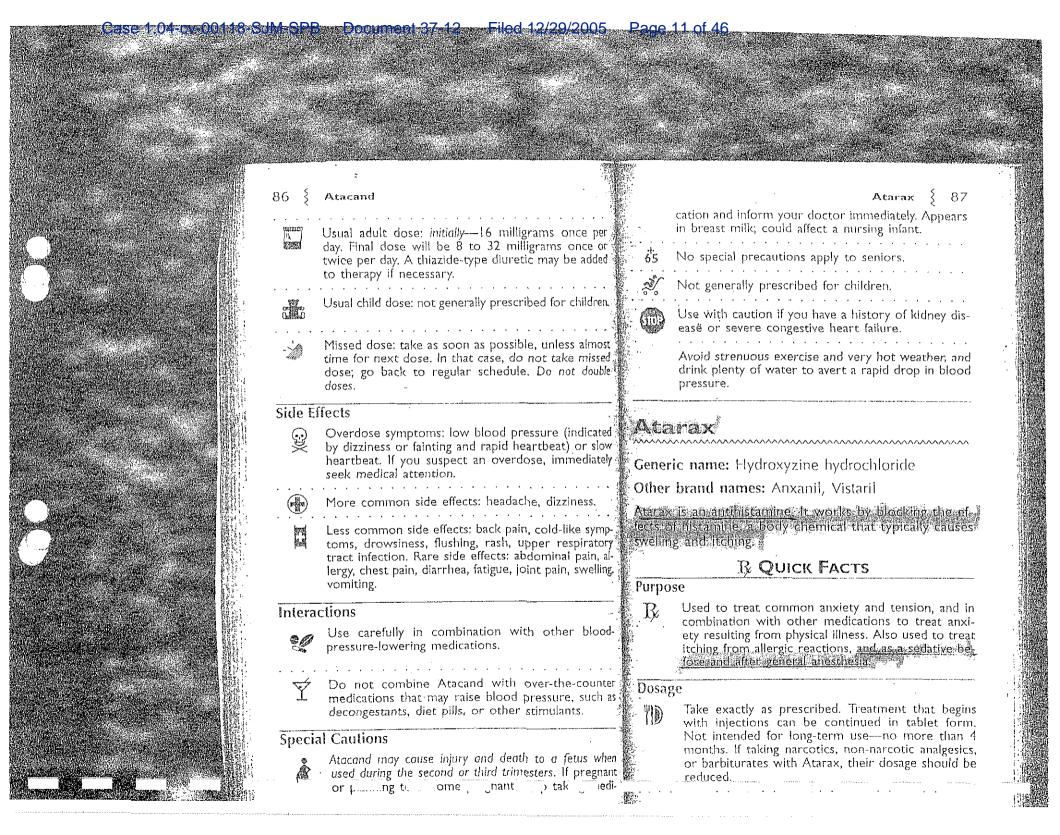
NOTE: As these drugs take effect, and mood begins to lift, the individual may have increased energy with which to implement a suicide plan. Suicide potential often increases as level of depression decreases. The nurse should be particularly alert to sudden lifts in mood.

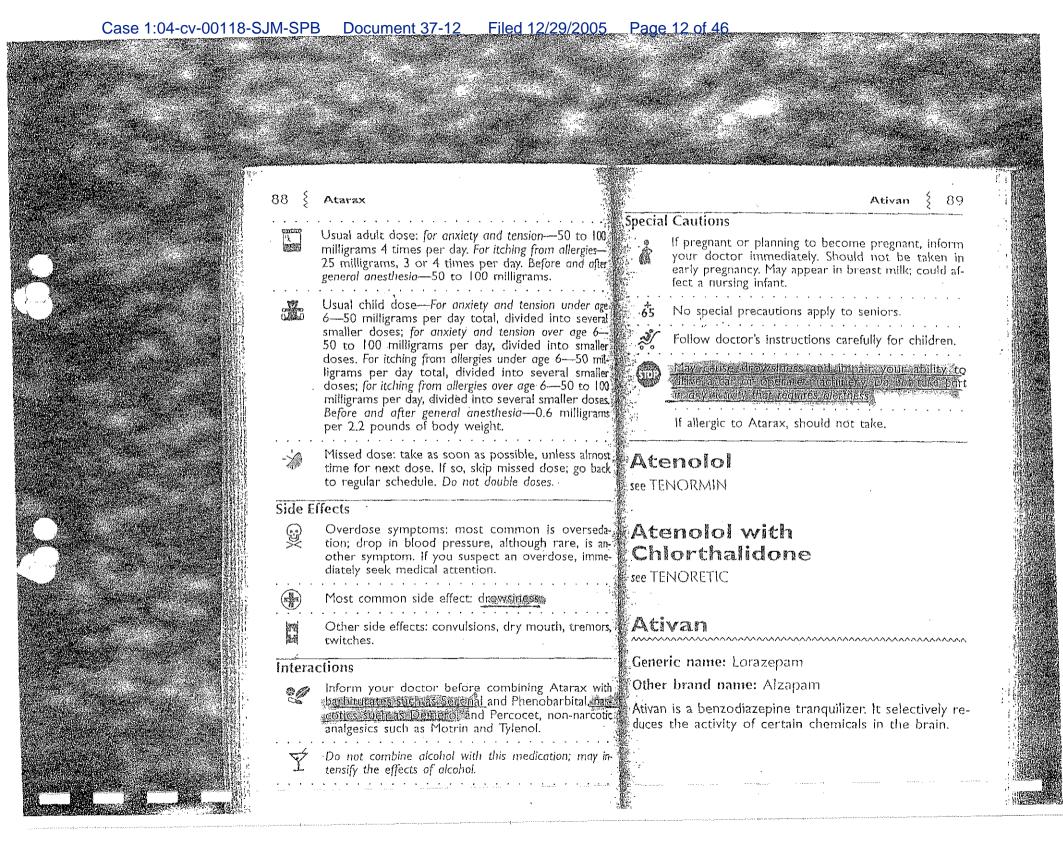
Examples of Commonly Used Antidepressant Medications (by Chemical Broup) and the Daily Adult Bosage Range

NOTE: Dosage requires slow titration: onset of therapeutic response may be 1 to 4 weeks.

Chemical	Generic (Trade)	Daily
Стопр	Name	Dosage Range
Unicyclic	bupropion (Weilbutrin)	200~450 mg
Bieve!ic	fluoxetine (Prozac)	20 - 80 mg
Tricyclics	amitriptyline (Elavil)	75-300 mg
	amoxapine (Asendin)	100-600 mg
	clomipramine (Analranil)	75 – 150 mg
	desipramine (Norpramin)	75-300 mg
	doxepin (Sinequan: Adapin)	30-300 mg
	imipramine (Tofranii)	T5 = 300 mg (continued)

# AntianxietyAgents the Appellant was Prescribed





## Appendix N

Case 1:04-cv-00118-SJM-SPB Document 37-12 Filed 12/29/2005 Page 14 of 46 19 March 1999 CONFINEMENT ORDER Prepare in duplicate. Original is retained by Confinement Officer; duplicate is returned to officer directing the confinement. The normal period for preferring court-martial charges following restraint of accused is 24 hours. (As to who may direct confinement, see paragraph 21a, MCM 1951.) INSTALLATION Confinement Officer MANNHEIM CONFINEMENT FACILITY THE PERSON NAMED BELOW WILL BE CONFINED LAST NAME - FIRST NAME - MIDDLE INITIAL GRADE SERVICE NUMBER/ DEPARTMENT OF MILITARY SERVICE SSAN ARMANN, Kurtis E. E-1U.S. Army ORGANIZATION A Company, 127th Aviation Support Battalion, APO AE TYPE OF CONFINEMENT OFFENSE(S) AND UCMJ ARTICLE(S) VIOLATED PRETRIAL X RESULT OF Article 80 (Attempted murder), Article 81 COURT-MARTIAL (Conspiracy to commit premeditated murder), Article 92 (Violate a general regulation), Article 112a (Wrongful use of marijuana) SIGNATURE OF OFFICER ORDERING CONFINEMENT for authorized TYPE OR PRINTED NAME, GRADE AND TITLE OF OFFICER ORDERING CONFINEMENT (Or authorized representative) COLLEEN M. COYNE, CPT, JA Assistant Trial Counsel RECEIPT FOR PRISONER THE PRISONER NAMED ABOVE WAS RECEIVED FOR CONFINEMENT HOUR DATE P

ORGANIZATION

, 29724

APO

SIGNATURE OF CONFINEMENT DEFICER (Or authorized representative)

D FORM 497, 1 MAY 66 (EG) REPLACES DD FORM 497, 1 SEP 53, WHICH IS OBSOLETE.

TYPED OR PRINTED NAME AND GRADE OF CONFINEMENT OFFICER

MCGILL BRIDGET

(Or authorized representative)

556, USA

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## Appendix O



October 4, 2000

Ms. Jimonique Rodgers USALSA - Defense Appelate 901 North Stuart Street Arlington, VA 22203

Dear Ms. Rodgers:

Thank you for contacting Roche regarding Accutane® (isotretinoin). As you have requested, we are enclosing a package insert.

Please note that the package insert, also called the prescribing information, contains a great deal of technical information. It is designed to help health care professionals understand what we have learned about this product. If you have any questions, we urge you to discuss them with your doctor or pharmacist.

If we can be of further assistance, please do not hesitate to contact us. Thank you for your interest in Roche.

Cordially,

Roche Pharmaceuticals Service Center 1-800-526-6367

/bc Enclosure Case 1:04-cv-00118-SJM-SPB

Document 37-12

Filed 12/29/2005

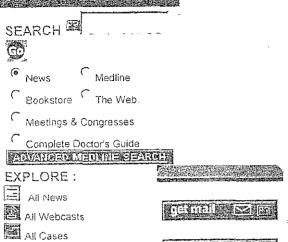
Page 23 of 46











FDA Reports Accutane May Be Linked To De

ROMA STEELS OF THE STATE OF THE

WASHINGTON, MD # February 26, 1998 - The Unite Food and Drug Administration is advising consumers. care providers of new safety information regarding the prescription antifache drug Accutane usotretingin) anc. reports of depression, psychosis and rarely suicidal th

actions. A

Suicide

Accutane was approved in 1982 to treat only a very sp of acne - severe nodular acne that has not responded therapies.

Warning | Privacy | Awards

Although the Accutane label already included informat regarding depression as a possible adverse reaction, I felt health care providers and others needed additiona information as a result of adverse event reports the ag

received.

All Meetings & Congresses

All Medical Resources

Favourite Journals

Click here to choose your favourite journals

DG Quick Survey

New drugs / indications

English Dictionary

Medical Dictionary

Thesaurus

Favourite Sites 🖼

Click here to choose your favourite sites

In the past month, what percentage of your patients brought you health-related information they found on the

Languages 🖾

Make this your start page

Internet? C 0%

C 1-5% 6-10%

C 11-20% C 21-25%

More than 25%

FDA and the drug manufacturer are strengthening this warning, even though it is difficult to identify the exact these problems. Such problems could already be more among the patient populations likely to be on the drug

However, because some patients who reported deprereported that the depression subsided when they stop the drug and came back when they resumed taking it, and the manufacturer felt the strengthened labelling w warranted as a precautionary measure.

Given the complex nature of depression and suicidal c the new label information will advise health care provide merely discontinuing the drug may be insufficient to re adverse events and that further evaluation may be nec

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FDA warns of depression among patients using acne drug Accutane

Web posted Feb. 25 at 10:46 PM

Associated Press

CALEADAE

SPECIAL COVERAGES

SHOP SOUTH

CONTRACTOR OF THE PROPERTY OF

manufacturer Hoffman-La Roche. It said people with severe acne are at risk for depression anyway.

But the Food and Drug Administration counted about a dozen

WASHINGTON -- Doctors prescribing the powerful acne drug

says a warning issued Wednesday on the basis of reports of

There's no proof that Accutane caused the problems, argued

depression and a few suicides among Accutane patients.

Accutane should watch patients carefully for signs of depression,

But the Food and Drug Administration counted about a dozen patients who became depressed while taking Accutane, then found that their depression disappeared after they stopped the medication and recurred once they took it again.

That was enough of a link to prompt the precautionary warning, FDA said.

Roche wrote thousands of doctors Wednesday that it is relabeling.

Accutane to warm. Accutane may cause depression, psychosis and, a rarely, suicidal ideation, suicide attempts and suicide."

Patients should tell a doctor if they're feeling depressed, said FDA dermatologic drugs chief Dr. John Wilkin. And at every visit, doctors should ``ask questions to the patient about changes in mood," he said.

Roche officials refused to say how many depressed patients or suicides they know of but stressed that more than 4 million



- Shuttle Discovery
- Destroying Asteroids
- El Nino
- Viagra Craze
- Newsweek\_Website
- Microsoft Case
- Bell Atlantic

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Americans have taken Accutane since it was approved in 1982, and the possible side effect is very rare.

Roche also argued that teen-agers, prime acne sufferers, often suffer depression, and hormones involved with acne also may contribute to depression.

FDA officials also would not say how many depression and suicide reports among Accutane patients it has received but called them 'isolated." Wilkin emphasized that the estimated dozen patients whose depression occurred and then disappeared as they started and stopped Accutane were enough to suggest a link.

Accutane, considered a significant help to people with severe nodular acne, already carried a stern warning that it is never to be used by women who are pregnant or may become pregnant because it can cause birth defects.

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配 INFORMATION

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information:

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FATTANES

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beliefung text is complete prescribing in effect June 2000. text is complete prescribing information



TRAINDICATIONS AND WARNINGS: Accu-INDICATIONS AND WARNINGS: Accuments not be used by Jemoles who are preginant or his become pregnant while undergoing treated lithough not every letus exposed to Accutane thinked in a deformed child, there is an extremely lit that a deformed inlant can result if pregnancy with the taking Accutane is any amount even for pelode of time. Potentially any fetus exposed the following the accuracy of the period of the accuracy of the period of the accuracy of the period of the period of the accuracy which fetus has been affected and which letus and head of the period of the per

the is contraindicated in lemales of childbearing is unless the patient meets all of the following

here severe disfiguring nodular acne that is re-sent to standard therapies (see INDICATIONS URAGE for definition

be refusive in understanding and carrying out

of tapable of complying with the mandatory five measures required for Accutane ther Understand behaviors associated with an in-

Roying a latus to the drug large received both oral and written informa-tion types of contraceptive methods and shout the rates of possible contraceptive d of the need to use two separate, effective Epotraception simultaneously, unless absti

the shosen method, or the patient has un-anysterectomy and has acknowledged in the understanding of the information and and of the need for using two contracepdi simultaneousiv

of had a negative urine or serum pregnancy as a sensitivity of at least 50 mlU/mL when it qualified for Accutance therepy by the and must have had a second negative seem pregnancy test on the second day of terms menstrual period or at least 11 days feet unprotected act of sexual intercourse.

tand and agree that her prescriber will Pescription for Accutane only after she ve result for the second urine pregmake is to be conducted on the securificat normal menstrual period or at least the last unprotected act of sexual inter-Derrer is later

ectived instruction to join the Accutance here watched a videotupe, provided by prescriber, that provides information contine methods, possible reasons for provide information follows, and importance of using affectuations. fertion when taking teratogenic drugs.

Ital abnormalities related to Accutane

Lare been documented: CNS abnormal
Corebral abnormalities, cerebellar malocaphalus, microcephaly, cranial nerva ormality; external ear abnormalities interprinta, small or absent external tys abnormalities linetuding micropri-

theirmel; cardiovascular abnormalities; facial dysmorphis: cleft palate; thymus gland phnormality, parathy-roid hormone deficiency. In some cases death has oc-curred with serisin of the abinormalities previously noted. Cases of IQ scores less than 85 with or without phyloges CNS appromalities have also been reported dovious Cros automated have been reported. In addition, premature births have been reported. It is strongly recommended that a prescription for Ac-

It is strongly recommended that a prescription for Ac-cutane should not be issued by the prescriber undil a female patient has had negative results from two urine or serum pregnancy tests, one of which is performed in the prescriber's office when the patient is qualified for Accutane therapy, the second of which is performed on the second day of the next normal menstrusi period or 11 days after the last unprotected act of sexual inter-course, whichever is leter, it is also recommended that pregnancy testing and counseling about contraception and habituping associated with an increased risk of behaviors associated with an increased risk of and behaviors associated with an increased risk of pregnancy be repeated on a monthly basis. To assure compliance, the prescriber should not issue a prescription for a female patient, until after the second negative pregnancy rest result is obtained. In addition, the prescriber should prescribe no more than a 1-month supply of the drug for all Accutane patients and no automatic refills should be permitted. Roche will supply unine pregnancy test kits for female Accutane patients. for the initial, second, and monthly testing during

therapy. Effective contraception must be used for at least 1 month before beginning Accurace therapy, during therapy, and for 1 month following discontinuation of the apy even where there has been a history of infertility, unless due to hysterectomy. The patient must be counseled about and understand the limitations of any chosen contraceptive method. The patient must also understanding the inscription of the patient must also understanding the patient must be considered with any using two conderstand the risks associated with not using two con

derstand the risks associated with not using two contraceptive methods, even when one of the chosen methods is a bormonal contraceptive method. Any birth control method can fail. Therefore, it is critically important that women of childbearing potential use two effective forms of contraception simultaneously, unless absolute abstinence is the chosen method, even when one of the forms is a hormonal contraceptive method. Although hormonal contraceptives are highly effective, there have been reports of pregnancy from women who have used oral contraceptives, as well as injectable/implantable contraceptives, as well as injectable/implantable contraceptives method as the contraceptive only a single method of contraception, it is not known if hormonal contraceptives differ in their effectiveness when used with Accutane.

known if hormonal contraceptives differ in their effectiveness when used with Accutane. If a pregnancy does occur during treatment, the prescriber and petient should discuss the desirebility of continuing the pregnancy. Prescribers are encouraged to report all cases of pregnancy with specific information about the contraceptive forms used during Accutance thereps and for 1 month following therapy, either to the Roche Medical Services @ 1-800-526-537 or to the Food and Drug Administration MedWatch Program @ 1-800-FDA-1038.

Accutane should be prescribed only by prescribers who have special competence in the diagnosis and treat-ment of severe recalcitrant nodular acne, are experienced in the use of systemic retinoids, and understand the risk of teratogenicity if Accutane is used during pregnancy.

Prescribers who prescribe Accurane should use the Prescribers who prescribe Accurane should use the Pregnancy Prevention Programs kit provided by flo-the for the counseling of patients, should instruct the patient to participate in the Accutane Survey, and should receive medical education sponsored by Roche about effective contraception, the limitations of contra-ceptive methods and behaviors associated with an increased risk of contraceptive failure and pregnancy.

#### DESCRIPTION

Isotretinom, a retinoid, is available as Accutane in 10-mg, Isourectinom, a reutmoid, is available as accurant in 10-mg, 20-mg and 40-mg soft geintin capsules for oral administra-tion. Euch copsule also contains becowar, burylated by-droxyantsole, edecate disodium, bydrogenated system oil. Rokes, nydrogenated vegetable oil, and sovbean oil. Geiatria capsules-contoin giveern and parabeast methyl and pro-pyli, with the following dye systems: 10 mg — iron oxida credi and titanium dioxide; 20 mg — C Red No. 3, FD&C Blue No. 1, and titanium dioxide; 10 tog. — FD&C Vellow No. 6, D&C Yellow No. 10, and titanium dioxide.

No. 6. Deet. Tenow No. 10, and stramum disone. Chemically, isotretinon is 13-us-retinon acid and is related to both retinous acid and remod lyterma At. It is a yellow-orange to orange crystalline powder with a molecular weight of 300 44. The structural formula is:



#### CLINICAL PHARMACOLOGY

Experience is a rectaod, which when administered in pharmacologic dosages of 0.5 to 0.0 mg/kg/day minists secacous stand function and keratiolization. The exact mechanism of action of Accurane is tuknown.

Nodular Acne: Clinical improvement in nodular acne patients occurs in association with a reduction in sebum secre-

tion: The decrease in sebum secretion is temporary and is reinted to the dose and duration of treatment with Acquane, and reflects a reduction in sebaceous gland size and an inhibition of seosceous gland differentiation. Pharmacokinetics: Absorbation: Oral absorbation of loseretimos is aptimal when taken with food or milk. After administration of a single 30 mg and dose two 40-mg capacies of isotretimos to 15 healthy male subjects, maximum blood concentrations ranged from 167 to 459 mgm21 mean 256 nm mL; and were achieved in 1 to 5 hours mean 3.2 hours. The oral absorption of isotretimos is consistent with first-order kinetics and can be described with a linear two-compartment model. Notwird acuse does not size the absorption of the drug; in a 27-dos variety of isotretimos in 10 male patients with adduct acuse treated with an oral dose of 40 me bid, the mean peak concentrations ranged from 8 mgmL to 355 mgmL mean 250 mgmL and occurred at 2 to 4 hours after administration mean 2.9 hours, in these patients, the mean 2.50 minimum steady-state blood concentration of isotretation was 160 t 19 mgmL. The terminal climination half-life was consistent with that observed in normal subjects.

Distribution: Isotretinoin is more than 99.9% bound to

subjects. Distribution: Isotretinoin is more than 99.9% bound to plasma proteins, primarily albumin. Metrodism: After oral administration of isotretinoin. Metrodism: After oral administration of isotretinoin. Albumin concentrations of 4-axo-isotretinoin is the major metabolite identified in the blood. Maximum concentrations of 4-axo-isotretinoin is 71 and 199 agricult were achieved at 6 to 20 hours after oral administration of two 40-me capsules; the blood concentration of the major metabolite generally exceeded that of isotretinoin after 8 hours. Isotretinoin also undergoes isomerization to the all-trans-isomer, tretinoin, which is then metabolited in the corresponding 4-axo-metabolite; both have been detected. Both parent compound and metabolites are further metabolited into conjugates which are exercted. Elimination: Following administration of an 50-mg illumd suspension and any conjugates which are exercted suspension and any conjugates are ultimately exercted in the faces and arine is relatively cand amounts untail of 654 to 5356. The terminal elimination is all-file of software for interestinoin 18 to 30 hours. The mean elimination half-file of 4-axo-isotretinoin is 25 hours trange 17 to 50 hours. After both single and multiple doses, the accumulation ratio of 4-axo-isotretinoin to purent compound is 3 to 3.5.

INDICATIONS AND USAGE.

#### INDICATIONS AND USAGE

Score recolcurant nadular acre: Accutance is indicated for the treatment of severa recalcurant nadular acre. Modules are inflammatory lesions with a diameter of 5 mm or greater. The nodules may become suppurative or hemorrhande. Severa, by definition, means many as opposed to flew or several modules. Because of significant adverse of feets assented with its use. Accutant should be reserved for antispits with severe nodular gene who are unresponsive to conventional therapy, including systemic antispitues. In addition, for female patients of childbearing powerful, Accutant is indicated only for those females who are not pregnant used boxed CONTRAINDICATIONS AND WARN-INGS. Accutane is indicated for

INGS.
A stude course of therapy for 15 to 20 weeks has been shown to result in complete and prolonged remission of disease in many patients. If a second course of therapy is needed, it should not be initiated until at least 8 weeks after completion of the first course, because experience has shown that patients may continue to unprove while off Accurant The optimal interval hefore retreatment has not been defined for patients who have not completed skeletul growth tese WaRNINGS. Skeital: Hyperostosis and Premature Eulahysed Clusters. inhyseal Closures

#### CONTRAINDICATIONS

CONTRAINDICATIONS
Pregnancy: Category X, See boxed CONTRAINDICATIONS AND WARNINGS.

TIONS AND WARNINGS.

Altergia Reaccions: Accustance is contraindicated in patients who are hypersensitive to this medication or to any of its components. Accustance should not be given to patients who are sensitive to parabens, which are used as preservatives in the gelutin copsule (see PRECAUTIONS, Hypersensimo-

#### WARNINGS

WARNINGS
Psychiatric Disorders: Accutane may cause depression, psychosis and, carely, suicidal ideation, suicida attempts and suicide. Discontinuation of Accutane therapy may be insufficient; further availation may be necessary. No mechanish and price have been exhibited for these areasts less.

insufficient further avaluation may be necessary. No mecharistin of action has been established for these events Jese
ADVERSE REACTIONS: Psychiatric.
Pseudotumor Cerebri: Accurane use has been associated
with a number of cases of pseudotumor cereon thenign intracranial hypernansionl, some of which involved concerntiant use of tetracyclines. Concomitant treatment with tetrecyclines should therefore be avoided. Early signs and
symptoms of pseudotumor cerebri include psplittedema,
headache, nausea and vorniting, and vasual disturbances.
Parients with these symptoms should be screened for papilledema and, if present, they should be told to discontinue
Accurane immediately and be referred to a neurologist for
further diagnosis and care (see ADVERSE REACTIONS:
Neurological).

Neurologicali.

Panercettis: Acute panereatitis has been reported in patients with either elevated or normal serum trichyceride levels. In rare instances, fatal hemorrhagic panereatitis has been reported, Acutane should be stopped if hypertrighyc-

Continued on next page

Consult 2001 PDR+ supplements and luture editions for revisions





2722/ROCHE LABS

PHYSICIANS' DESK

#### Accutane--Cont.

erndemia cannot be controlled at an acceptable level or if

eridentia cannot be controlled at an acceptable level or if symptoms of pancreatitis cocur.

Lipida: Elevations of serum triglycerides have been reported in patients treated with Accutane. Marked elevations of serum triglycerides in excess of 800 mg/dL were reported in approximately 25% of patients receiving Accutane in dinical trials. In addition, approximately 15% developed a decrease in high-density lipoproteins and about 7% showed an increase in cholesterol levels. In clinical trials. showed an increase in timesection with a manufacture the effects on implycertules, HDL, and cholesterol were reversible upon cessation of Accutance therapy. Some patients have been able to reverse triglyceride elevation by reduction

have been able to reverse triglycoride elevation by reduction in weight, restriction of dietary fat and alcohol, and reduction in dose while continuing Accutane.

Blood lipid determinations should be performed before Accutane is given and then at intervals until the lipid response to Accutane is established, which usually occurs within 4 weeks. Especially careful consideration must be given to risiobanefit for patients who may be at high risk during Accutane therapy spatients with diabetes, obesity, increased alcohol liatake, lipid metabolism disorders. If Accutane therapy is instituted, more frequent checks of serum values for an instituted, more frequent checks of serum values for lipids and/or blood sugar are recommended (see PRECAU-TIONS: Laboratory Tests).

The cardiovascular consequences of hypertriglyceridem assonated with Accutant are unknown. Animal Studies: In rats given 8 or 32 mg/kg/day of isotrationin (9.7 or 2.7 times the maximum clinical dose after normalization for total body surriace area for 18 months or longer, the incidences of focal calcification, fibrosis and inflammation of the myocardium, calcification of coronary, pulmonary and mesenceric arteries, and metastotic cacification of the gostric mucosa were greater than in control rats of similar age. Focal endo-cardial and myocardial indirifications associated with calcination of the greater of the program arraises were observed in your doses. associated with Accutant are unknown, Animal Studies: In fication of the coronary arteries were observed in two dogs arier approximately 6 to 7 months of treatment with isocre-tinoin at a dosage of 50 to 120 mg/kg/day (15 to 30 times the maximum clinical dose, respectively, after normalization for

total body surface area).

Hearing Impairment: Impaired bearing has been reported Hearing Impairment. Impaired bearing has been reported in patients tabling Accutanes in some eases, the bearing impairment has been reported to persist after therapy has been disconcinued. Mechanismust and causality for this event have not been established. Pottents who experience tinnitus or hearing impairment should discontinue Accurate treatment and be referred to specialized care for further evaluation (see ADVERSE REACTIONS: Special Supersi.)

Hepatotoxicity: Clinical hepaticis considered to be possibly or probably related to Accurane therapy has been reported.
Additionally, mild to moderate elevations of liver enzymes
have been observed in approximately 15% of individuals
treated during clinical trials, some of which normalized with design reduction or continued administration of the drug. If normalization does not rendily occur or if hepatitis is suspected during treatment with Accusane, the drug should be discontinued and the enointy further investi-

should be these controlled and the property of the part of the par persist after Accurane treatment has been stopped. Patients

persist after Accurance treatment has been stopped. Fatients experiencing abdominal pain, neveral bleading or severe districtive should discontinue Accurance immediately user AD-VERSE REACTIONS: Constraints studied by Skeletak Phyperostosis: A night prevalence of skeletal hyperostosis was noted in clinical trials for disorders of keratimation with a mean does of 2.24 mg/kgrday. Additionally, skeletal hyperostosis was noted in 6 of 3 patients in a prospective study of disorders of keratimization. Minimal skeletal hyperostosis was noted in 6 of 3 patients in a prospective study of disorders of keratimization. Minimal skeletal hyperostosis was noted in 6 of 3 patients in a prospective study of disorders of keratimization. Minimal skeletal hyperostosis and education of light means and tendons. spective study of informers of real ultitudes, administ seen each hypersystosis and calcification of ligaments and tendons have also been observed by x-ray in prospective studies of nodular anne paperns troated with a single course of ther-py at recommended doses. The skeletal effects of multiple Accutance treatment courses for zone ore unknown. Premature Epiphysical Closure: There are spontaneous re-

Premature Engineeral Closure. There are spontaneous re-ports of premature corphyseal closure in acre patients re-ceiving recommended doses, but it is not known if there is a causal relationship with Accutane. In clinical strals for disorders of keraring ation with a mean dose of 2.24 makaday. orders of kerodination with a mean tose of the state of premature points seel closure. The skeletal effects of multiple Accutane treatment courses for aone are unknown. Vision imperiment: Visual problems should be carefully

monitorial All Accitane patients experiencing visual diffi-cutties should discontinue Accitane presiment and have an ophthalmological examination (see ADVERSE REAC-TIONS: Special Senses).

Comed Opacities: Corneal opacities have occurred in pa-tients receiving Accutane for acne and more frequently when higher drug dosages were used in patients with disor-ders of keraturusation. The corneal opacities that have been ders of Keratumation. The formest opacities that have endoserved in clinical trial patients steated with Accurane have either completely resolved or were resolving at follow-up 6 to 7 weeks after discontinuation of the drug (see ADVERSE REACTIONS). Special Sensess.

Decreased Night Vision: Decreased night vision has been reported during Accurane therapy and in some instances.

cause the onset in some patients was sudden, patients should be advised of this potential problem and warned to be cautious when driving or operating any vehicle at night.

#### PRECAUTIONS

Information for Patients and Prescribers: Females of information for patients and Prescribed that they must not be pregnant when Accutane therapy is initiated, and that they should use effective contraception while taking that they should use energive contraception while candidate Accutane and for 1 month after Accutane has been stopped. They should also sign a consent form prior to beginning Accutane therapy. They should be instructed to join the Accutane Survey and to review the patient videotape provided by Roche to the prescriber that provides intage provided by notice to the most common reasons that contraception fails, and the importance of using effective contraception when taking terracopied drups. Female patients should also be seen monthly and have a urine or patients should also be seen monthly and have a other serum pregnancy test performed each month during treatment to confirm negative pregnancy status (see boxed CONTRAINDICATIONS AND WARNINGS).

Patients should be informed that they must not share Accutance with anyone else because of the risk of birth de-

- cutane with anyone else because of the risk of which of fects and other serious adverse events. Patients should not donate blood during therapy and for I month following discontinuance of the drug because the blood might be given to a pregnant woman whose fetus must not be exposed in Augurane.
- must not be exposed to Accutance.

  Patients should be informed that transient expectation (flural of Jone has been seen, generally during the initial period of therapy.

  Was epilation and skin resurfacing procedures (such as dermabrasion, leser) should be avoided during Accutance therapy and for at least 6 months thereafter due to the possibility of scarring (see ADVERSE REACTIONS: Skin and Appendixts). and Appendagest
- Patients should be advised to avoid prolonged exposure to
- TV rays or smilight.
  Patients should be informed that they may experience de-creased tolerance to contact leases during and after ther-
- apy.
  Patients should be informed that approximately 16% of patients treated with Accusine in a clinical trial devel-oped musculoskeletal symptoms (including arthratigial during trentment. In general, these symptoms were mild to moderate, but occasionally required discontinuation of to moderate, but occasionally required discrimination to the drug. Transient poin in the chost has been reported less frequently. In the clinical trial, these symptoms gen-erally cleared rapidly after discontinuation of Accusane, but in some cases persisted (see ADVERSE REACTIONS: Musiculoskeletath.
- Meutropenia and rare cases of agranulocytosis have been reported. Accutane should be discontinued if clinically significant decreases in white cell counts occur.

Hypersensitivity: Anaphylactic reactions and other allergic regenerations, and interest reactions are reactions have been reported. Outsineous altergic reactions and serious cases of altergic vascuilitis, often with purpurations and red patches) of the extremities and red patches; of the extremities and extraculaneous involvement uncluding renait have been reported. Severe allergic renedon necessitates discontinuation of ther app and appropriate medical management.

#### Drug Interactions:

- Because of the relationship of Accutone to vitamin A. 20 declared of the relationship of specific to strain supplier should be advised against taking strainin supplier ments containing strainin A to evoid additive toxic efforts. Concomitant treatment with Accutance and tetracyclines
- should be avoided because Accurane use has been ass should be dynamic seconds of pseudotumor cerebri do-ated with a number of cases of pseudotumor cerebri do-nign intracranial hypertension), some of which involved concomitant use of tetracyclines.
- conconitant use of tetractelines. Microdused progestorate preparations (mutipilis) may be an inadequate method of contrategation during Accurance therapy. Although other hormonal contracequires are highly effective, there have been reports of areamony from women who have used oral contraceptives, as well as injectable/miplantable contraceptive products. These reports are more frequent for women wan use only a single method of contraception. It is not known if hormonal contraceptives differ in their effectiveness when used with Accusance. Therefore, it is retically important that women traceptives offer in thair enecutiveness when beet wan Accusane. Therefore, it is entically important that women of childbearing potential use two effective forms of contra-ception simultaneously, unless absolute abstinence is the chosen method, even when one of the forms is a formonal contraceptive method (see boxed CONTRAINDICATIONS AND WARNINGS).

#### iooratory Tests:

- Prygnancy Test: Female nationts of childbearing potential Programy Test Permie patients of chitobouring potential must have negative results from two units or serving regenancy tests with a sensitivity of at least 30 mIU mL before a presemption is given. The first test is to be permitted at the office visit when the patient is qualified for Accutane therapy by her presenter. The second test is to be performed unithe second day of her next mensional color of 11 days after her last amortacetted act of sextial intercourse, whichever is later. Additional pregnancy tests to be before the day and the second of the color of the second of the color of the second of the color of the second are to be conducted monthly dumne treatment
- are to be conducted monthly during treatment.
  Lipida: Pretreatment and following blood lipids should be obtained upder fiscing conditions. After consumption of alcohol, at least 36 hours should elapse before these determinations are made. It is recommended that there exists be performed at weekly or Sweekly intervals until the lipid response to Accutance is established. The indicator of hitpertrial vendence is a statistical.

- Liver Function Tesis: Since elevation have been observed during clinical has been reported pretreatment and in the has been reported pretreatment and sensition tests should be performed at realistations and the response to Accuracy Blanca see WARNINGS: Repotential Tests.
- Glucose: Some patients receiving Accura-enced problems in the control of their bla-dition, new cases of diabetes have been a Accurance therapy, although no causaly heen established.
- TPK Some potients undergoing vigority
  while on Accurant therapy have expended
  CPK levels; however, the clinical significa-Circinopenesis. Mutagenesis and Impairies In maie and female Fischer 344 rats given at dosages of S or 32 mg/kg/day (0.7 or 2.7 kg/day at dosages of so the mysergary 10.7 or 2.1 mm mum chinical dose, respectively, after member body surface areas for greater than 18 month dose-related increased unclease of phecolomous to controls. The incidence of afternal members to controls. The incidence of afternal members are sufficiently of the higher doses. plusic was also increased at the higher door. At The relatively high level of spontaneous mass occurring to the male Fischer 241 of sequivocal model for study of this tumor the vance of this tumor to the human population. The Ames test was conducted with isometical The Ames test was conducted with sorreined ratories. He results of the tests in one labelly acree while in the second laboratory i welly sponse tless than 1.6 x background was being murium TA100 when the assay was merubolic activation. No dose-response that metabolic activation. No dose-response that all other strains were negative. Additionably, signed to assess genotoxicity (Chinese hampir muses micronucles test. S. cercurine Distinguishments assessed with human-derived brains unscheduled DNA synthesis assay) were all principles. The adverse education gondal function for the properties rouse, gestation or parturition were all desires of isotretination of 2.8, or 32 migration. 2.7 times the maximum clinical dose, respective In does, testicular atrophy was noted that or i scottering of the does, testicular atrophy was noted that or i scottetinoin for approximately 30 weeks 20 or 50 mg/kg/day 5 or 15 times the hard 20 or 50 mg/kg/day i5 or 15 times the flating dose, respectively, after normalization for feel pareal. In general, there was introscopic or ridge in circle in control of the second of the circle depression of spermatogenesis but stop observed in all testes examined and in the completely arropine tubules seen. In attack if whom were patients with nodular acme with oral softeninn, no significant changing the count or motility of spermatozes in the standard particular control of the count of motility of spermatozes in the standard particular control of the count of motility of spermatozes in the standard particular control of the count of motility more seen an ajaculate volume, sperm or motility more node of the count of the c

Pregnancy: Category A. See done of the TIONS AND WARNINGS.

Narsing Mathers: It is not known whether the crosed in human milk, Because of the patents of the

ADVERSE REACTIONS ADVERSE REACTIONS
Clinical Trials and Postmarketing Surveilland
verse reactions listed below rofted the spirit
vestigational studies of Accurance, and this proevenement. The relationship of some of their
cutant therapy is unknown. Many of the liber
perse recictions seen in patients receiving Addition
that to those described in patients table 1997. ilar to those described in patients when the victoria A drivers of the skin and normal within the lips, massi passone, and eyest."

Dosa Relationship: Chelitris and hyperty usually dose related. Most adverse restaud, dose the clinical tradis were reversible when hearty and however, some persisted after cases.

WARNINGS and ADVERSE REACTIONS. Bair as a Whole: allerge rescions, indexis, systemic hypersensitiver see PRECAUTION release, fedigue, lymphadenopality, and the control of th Corriocascular: naipitation, tachytaria

unic discuse, stroke

Endocrine Metabolic: hypertrigiyaning
INGS: Lipidas, alterations in blood sarCALTIONS: Laborator Tests

Gustroin testinal: indiamatic Superintensistings innaminatory broad-DIGS: Interminatory Botted Disease, bend-INGS: Mentionaristicy, panersating to the broading and innamination of the state of the superintensial su nouses, other nouspecific gastronisminal Fit Memorioner: where reactions uses Experience to the presentation uses a supersensation, among the presentation of patients and Prescription union for Patients and Prescription Continues and Prescription Continues and Prescription Continues and Continue Musculosketetal: sketetal hyperostas, and dens and ligaments, premature epith WARNINGS. Selectal: mild to modificate symptoms including arthralen isse PROMITED and the process of the selection of the process of the selection of

#### DUCT INFORMATION

arthricis, tendonitis, other types of hone ab-

descar pseudocumor cerebri isas WARNINGS: immor Cerebri, dizmass, drowainess, headache, in-things, malaise, nervousness, pareschestas, sei-thing troppe, weakness

chheron maiatse, nervousness, parestnestas, sende, sumone, wenkness
suiddal ideaton, suidde attempts, suidde, suychosis teee WARNINGS: Psychotic Disorpropional instability

pational instability
patients reporting depression, some reported that the
continuous of therapy and re-

cients reporting depression, some reported that the subsidied with discontinuation of therapy and resident principles of the subsidied with discontinuation of therapy and resident processing the subsidied with discontinuation of therapy and resident processing the subsidied without a history of all respiratory infection, voice alteration of the processing the subsidied processing the subsidied of the subsidied

Sense: Hearing hearing impairment isse WARN-Tearing Impairment), tionitus, Vision: corneal opne-tioning Impairment, tionitus, Vision: corneal opne-tioning Impairment of Corneal Opne-tioning Impairment of Corneal Opne-tioning Impairment of Corneal Opne-tioning Impairment of Corneal Opne-Tearistic, color vision disorder, conjunctivitis, dry which inflammation, keratilis, ootic neurisis, phope-

sateracts, color vision disorder, conjunctivitis, dry splat inflammation, keratitis, optic neuritis, photo-friend dissurbances

Aprium: glamerulomenhritis isee PRECAUTIONS: Riddity), nonspecific urogenital findings isee PRE-Mys. Laboratory for other urological parameters; Elevation of plasma trigiperides isee WARN. Edidal, decrease in serum high-density lipoprotein firels, elevations of serum cholesterol during treat-

All the phosphatase, SGOT (AST), SGPT (ALT), SGPT (ALT), SGPT (ALT), SGPT (ALT), SGPT (ALT), SGPT (ALT), SGPT (AST), SGPT (AST

hatelet counts, thrombecytopenia is in the urine, proteinuria, microscopic or gross

#### SAGE

AGE

July of isotretinoia is greater than 4000 mg/kg in jise (2,000 times the maximum clinical dose after than 4000 mg/kg in the nations clinical dose after normalization is dose for total body surface area) and is approximately approximately considered the maximum clinical dose after normalization is dose for total body surface area). The maximum clinical dose after normalization for total body surface areal, it is a surface and the maximum control of the surface areal, it is a surface and the surface areal, it is a surface and the surface areal, it is a surface and the surface area and the surface area.

#### NO ADMINISTRATION

granded dosses range for Aucutaine is 0.5 to 2 method dosses daily for 15 to 20 weeks. In English 0.1, 0.5, and 1 mykg/day' it was found songes provided initial elearnes of disease, but greater need for retreatment with the tower ion.

ed that for most parients the initial cosage

oded that for most patients the initial dossage of the 10.5 to 1 mykerday. Patients whose disease is a primarily manifested on the trunk may relieve the maximum recommended dossage. 2 mykey treatment whose may be adjusted according to disease and/or the appearance of clinical tome of which may be dose reluted that count has been reduced by more than the appearance of clinical count has been reduced by more than the appearance of the appeara

manure, must be followed for any subse-fiberary (see boxed CONTRAINDICATIONS

be administered with food.

carles, 10 mg (light pink), imprinted ACCU-LIE Boxes of 100 containing 10 Prescription of ODC 0004-0155-491.

Jack, 20 mg 'marcont, imprinted ACCU-Excess of 100 containing 10 Prescription a (NDC 0004-0169-49).

#### ROCHE LABS/2723

#### ACCUTANE DOSING BY BODY WEIGHT

Body V	Varent	3001	NEIGHT	
zilograms	pounds	0.5 mg/kg	Total Mg/Day	
<b>‡0</b> 50	\$8	20	l makg	2 mg/kg
50 50	110 132	2ā	40 50	50
70 30	154	30 35	50	100 120
90 100	176 198	40	70 80	140 160
0 1	230	45 50	100 30	190

Soft gelatin capsules, 40 mg (yellow), imprinted ACCU-TANE 40 ROCHE. Boxes of 100 containing 10 Prescription Paiss of 10 capsules (NDC 0004-0156-49).

Store at controlled room temperature (59° to 86°F, 15° to 30°C, Protect from light.

#### REFERENCES

30°C. Protect from ingit.

REFERENCES

1. Peck GL. Olsen TG. Yoder FW. et al. Prolonged remissions of cystic and congloboue acne with 13-cis-rotinoic acid. N Engl J Med 300:329-333, 1979. 2. Pochi PE. Shalita AR. Strauss SJ. Webster SB. Report of the consensus conference on acne classification. J Am Acad Dermatol 24:495-500. 1991. 3. Ferrell LN. Strauss JS. Strauseri AM. The treatment of severe cystic acne with 13-cis-rotinoic acid evaluation of sebum production and the clinical response in a multiple-dose trial. J Am Acad Dermatol 3:600-611, 1860. 4. Jones H. Blanc D. Cunliffe WJ. 13-cis-rotinoic acid and acne. Lanct 2:1048-1049, 1980. 5. Kur RA, Jorgenson H. Nigra TT. Elevation of serum trighteeride levels from oral isouretinoin in disorders of kerntinization. Arch Dermatol 116:1369-1372, 1980. 5. Ellis CN. Molison KC, Pennes DR. Martel W. Jonese SJ. Isotratinoin therapy is associated with early skeletal radiographic changes. J Am Acad Dermatol 10:1024-1029, 1984. 7. Dicken CH. Connoilly SM. Eruptive vanthomas associated with carrieron (13-eserciation) and control of the control of the property of the control of

PATIENT CONSENT FORM:

To be completed by the patient, her parent/guardian\* and signed by her prescriber.

Please read each item below and initial in the space provided to indicate that you understand each item and agree to follow your prescriber's instructions, DO NOT SIGN THIS CONSENT AND DO NOT INDERSTAND, DO NOT SIGN THIS SANYTHING THAT YOU DO NOT UNDERSTAND. A parent or guardian of a minor patient must also read and understand each item before signing the consent.

1. I.

I, Patient's Numer understand thus Accutane is a very powerful medicine with the potential for serious Adverse Effects that is used to treat severe nodular acne that did not get better with other treatments including oral antibiotics.

I understand that I must not take Accutane lisotretinoin if I am pregnant. I understand that I must not take
Accutane if I am nole to become pregnant and I am not
using the required two separate forms of effective methods of birth control.

#### INITIALS:

Junderstand from my prestrier that although not overy fetus exposed to Accustane has resulted in a deformed child, there is an extremely high risk that my unborn abuy could have severe birth defects if I am pregnant or become pregnant while taking Accustane in any amount even for short periods of time. Potentially any fetus exposed during premaier on be affected. any amount even acc soort periods of time. Forting any fetus exposed during pregnancy can be affected.

INTIALS:

I understand that I must avoid pregnancy during the entire time of my treatment and for 1 month after the end of my treatment with Accutance.

[NITIALS:

I understand that if I am able to become pregnant and unless I absolutely and consistently abstain from sexual intercourse, I must use two separate, effective forms of birth control fourtraception. AT THE SAME TIME, INSTEALS:

I understand from discussions with my proscriber that birth control pills and injectable/implantable birth control pills and injectable/implantable birth control products are the most effective forms of birth control. I understand that there have been reports of pregnancy from women who have used hirth control pills, as well as women who have used injectable/implantable birth control products and I understand that pregnancies occur more often when only a single method of birth control products and it is essential that it is establed implantable burth control products.

NITIALS:

I understand that the following are considered effective

I understand that the following are considered effective forms of contraception:

forms of contraception:
Primary: Tuola ligation, partners vasectomy, birth
control pills, injectables implantable birth
control products, and an ECD
Secondary: Disphragms, latex condoms, and cervical
caps; each must be see with a spermicide.
I understand that at least one of my two chosen methods
of birth control must be a primary method, and that any

birth control method can fail, even when two forms are used at the same time.

#### INITIALS:

I understand that I may receive free initial contracep-tive counseling and pregnancy testing from a consulting physician or family planning center. I understand that my Accutane prescriber can provide me with an Accu-8. tane Patient Referral Form for this consultation.

INITIALS: \_ I understand that I must begin actively avoiding preg-I contracted that I must organ account around prevancy around prevancy as described above at least I month before taking the first dose of Accutane, throughout treatment with Accutane and for I month after I have completed Accutane treatment.

#### INTLALS

INITIALS:

10 I understand that I cannot receive a prescription for Accurance uniess I have ? negative premancy test results. The first pregnancy test should be during the focusion. The second test should be on the second day of my next mensional cycle or 11 days after the last time I had unprotected sexual intercourse, whichever is later. I understand that I will have additional pregnancy testing, monthly, throughout my Accurance therapy. monthly, throughout my Accurance therapy, INITIALS:

11. I understand that I should not start Accutane until I am sure that I am not prognant and have negative results from 2 prognancy tests.

#### INITIALS:

12. I have read and understand the materials my prescriber . I have read and understand the materials my prescriber has given to me, including the brachure important information Concerning Your Treatment with Accusane® insorterinain. I have watched and understand the Roche video provided to me by my prescriber about contraception. Thave also been told about a confidential counseling line that I may call for additional information about birth control and I have seeinful information about birth control and I have received information on emergency contraception.

#### INITIALS:

13. I understand that I must not share my medication with anyone eito and that I should not give blood until I month after taking my last dose of Accutane, because if I do, someone else's unborn baby may be exposed to Acсптале,

#### INITIALS:

14. I understand that I must immediately stop taking Accutone and inform my prescriber if I become pregnanc. miss my menstrual period, or stop using birth control.
INITIALS:

15. I have been given information about the confidential Accustance Survey by my prescriber and heighe has explained to me how important it is to join the Accustance.

My prescriber has answered all my questions about Accu-My prescriber has answered all my questions about accu-tane and the Accurane information provided to me. I under-stand all the information of have received and that avoiding pregnancy during Accurance treatment is my responsibility. INITIALS:

with Accutane.	authorize	pegin	my	prescrib trentnie:
Patient signature	<del> </del>			Date
Parent/guardian sig	расиле		_	Date

Please print; Patient name and address

#### Telephone (area code)

fully explained to the the nature and purpose of the treatment described above and the neks to females of childbearing potential. I have asked the patient if she has any questions regarding her treatment with Accurane and have answered those questions to the best of my ability.

Prescriber signature

"if patient is a minor under the age of 18.

Roche Pharmaceuticals
Roche Laboratories Inc., 340 Kingsland Street, Nutley, New Jersey 07110-1199

Revised: May 2000

Shown in Product Identification Guide, page 332

Continued on next page

Consult 2001 PDR4 supplements and future editions for revisions

#### APPENDIX C

Copy 1 . Volume <u>I</u>.of <u>II</u>

#### VERBATIM

#### RECORD A Second

(and accompanying papers)

Of

ROESELER, David M.

(Name: Last, First, Middle Initial)

(Social Security Number)

Specialist

(Rank)

A Company, 127th Aviation Support Battalion, US Army, APO AE 09165

(Unit/Command Name)

(Branch of Service)

(Station or Ship)

Вγ

#### GENERAL COURT-MARTIAL

Convened by THE COMMANDER

(Title of Convening Authority)

#### CORPS

(Command of Convening Authority)

Tried At

Hanau,

Federal Republic of Germany

(Place or Places of Trial)

On

28 July 1999

(Date or Dates of Trial)

ALLIED PAPERS

MPANION CASES:

TARBOX, ROY P. ARMY9900182-P.3

Hate Complete

A Co, 127th ASB, US Army

APO AE 09165

LUND, Jeremy J. AR Myggoo116-P.3 PVT,

DPC

A Co, 127th ASB, US Army APO AE 09165

125 ARMANN, Kurtis E. ARM YGGOO316-P3

A Co, 127th ASB, US Army

APO AE 09165

OIE. Monica S. ALMV 9900436-P3

B Co, 127th ASB, US Army APO AE 09165

GIBSON, Scott D. ARMYOGO 0573-A3

B Co, 127th ASB, US Army

APO AE 09165

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Copy 1 Volume I of II

Front Cover

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Previous editions are obsolete

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#### DEPARTMENT OF THE ARMY Headquarters, V Corps APO AE 09014

GENERAL COURT-MARTIAL ORDER NUMBER 47

10 December 1999

SPC David M. Roeseler, Julian D., U.S. Army, A Company, 127th Aviation Support Battalion, APO AE 09165, was arraigned at Hanau, Germany, on the following offenses at a general court-martial convened by Commander, V Corps.

Charge L Article 80. Plea: Guilty. Finding: Guilty.

Specification 1: Attempted premeditated murder with a firearm, at or near Hanau, Germany, on or about 10 October 1998. Plea: Guilty. Finding: Guilty.

Specification 2: Attempted conspiracy to commit premeditated murder, at or near Hanau, Germany, between on or about 1 February 1998 and 1 April 1998. Plea: Guilty. Finding: Guilty

Charge II. Article 81. Plea: Guilty. Finding: Guilty.

The Specification: Conspiracy to commit premeditated murder, at or near Hanau, Germany, between on or about 1 March 1998 and 10 October 1998. Plea: Guilty, except the words "and gather information on Private First Class Toni A. Bell's schedule", substituting therefore the words "and provide information on Private First Class Toni A. Bell". To the excepted words: Not Guilty. To the substituted words: Guilty. Finding: Guilty.

#### SENTENCE

Sentence was adjudged on 28 July 1999. To forfeit all pay and allowances, to be reduced to the grade of Private E1, to be confined for a period of 19 years, and to be discharged from the United States Army with a dishonorable discharge.

#### ACTION

Only so much of the sentence as provides for forfeiture of all pay and allowances, reduction to

NCOIC, Criminal Law Division

GCMQ No 47, HQ V Corps, APO AE 09014, dated 10 December 1999

the grade of E1, confinement for fifteen years, and a dishonorable discharge is approved and, except for the part of the sentence extending to a dishonorable discharge, will be executed.

BY COMMAND OF LIEUTENANT GENERAL RILEY:

#### DISTRIBUTION:

1 Each Individ concern

1 LTC Wright (MJ)

1 CPT Coyne (TC)

1 CPT Zipf (DC)

1 Cdr, U.S. Army Discolinary Barracks, Ft. Leavenworth, KS 66027-1363

1 Cdr, A Co, 127th Avn Sup Bn, APO AE 09165

1 Cdr, 127th Avn Sup Bn, APO AE 09165

1 Cdr, Det A, 55th PSB, (Attn: Records Section), APO AE 09165

2 SJA, V Corps, APO AE 09014

1 Record Set

1 Reference Set

1 Cdr, HQ Det, 39th Finance Battalion, APO AE 09165

1 Cdr. USAEREC, ATTN: PCRE-FS, Fort Benjamin Harrison, IN 46249

10 Clerk of Court (JALS-CC), Nassif Bldg, Falls Church, VA 22041-5013

#### VERBATIM

#### RAA RECORD

(and accompanying papers).

Of

TARBOX, Roy P.

(Name: Last, First, Middle Initial)

(Social Security Number)

Specialist

(Rank)

Company, 127th Aviation Support Battalion, US Army, APO AE 09165

(Unit/Command Name)

(Branch of Service)

(Station or Ship)

B٧

#### GENERAL COURT-MARTIAL

Convened by THE COMMANDER

(Title of Convening Authority)

CORPS

(Command of Convening Authority)

Tried At

Hanau.

Federal Republic of Germany

(Place or Places of Trial)

on 6, 28 and 29 January 1999

(Date or Dates of Trial)

COMPANION CASES: ARMANN, Kurtis E.

ARMY9900316-CMCR

Private.

A Co, 127th ASB

APO AE 09165

ARMY 9900116-P.3

LUND, Jeremy J.

Specialist.

A Co, 127th ASB

'APO AE 09165

Other Companion Cases To Follow Pending Referral

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CLERK OF COURT

See inside back cover for instructions as to preparation and arrangement 3/13038

Copy 1 Volume I of III

Front Cover

## DEPARTMENT OF THE ARMY Headquarters V Corps APO AE 09014

GENERAL	COURT-MARTIAL	ORDER
NUMBER		22

25 May 1999

SPC Roy P. Tarbox, U.S. Army, A Company, 127th Aviation Support Battalion, APO AE 09165, was arraigned at Hanau, Germany, on the following offenses at a general court-martial convened by Commander V Corps.

Charge I. Article 80. Plea: Not Guilty. Finding: Guilty.

The Specification: Attempted premeditated murder with a firearm, at Hanau, Germany, on or about 10 October 1998. Plea: Not Guilty. Finding: Guilty.

Charge II. Article 81. Plea: Not Guilty. Finding: Not Guilty of conspiracy to commit premeditated murder, but Guilty of conspiracy to commit aggravated assault.

The Specification: Conspiracy to commit premeditated murder, at Hanau, Germany, between on or about 1 July 1998 and 10 October 1998. Plea: Not Guilty. Finding: Not Guilty of conspiracy to commit premeditated murder, but Guilty of conspiracy to commit aggravated assault.

#### SENTENCE

Sentence was adjudged on 29 January 1999. To be reduced to the grade of E1, to total forfeiture of all pay and allowances, to be confined for two (2) years, and to be dishonorably discharged from the service.

#### ACTION

The Sentence is approved and, except for the part of the sentence extending to a dishonorable discharge, will be executed.

BY COMMAND OF LIEUTENANT GENERAL HENDRIX:

DISTRIBUTION:

l Each Individ concern

1 LTC Donna Wright (MJ)

Juny M. Gurk

AMY M. FRISK

LTC, JA

Chief, Criminal Law Division

#### GCMO No 22, HQ V Corps, APO AE 09014, dated 25 May 1999

- 1 CPT Carlene K. Christie (TC)
- 1 MAJ Craig A. Meredith (ATC)

- 1 CPT Jason B. Libby (DC)
  1 Cdr, A Co, 127th Avn Spt Bn, APO AE 09165
  1 Cdr, 127th Avn Spt Bn, APO AE 09165
  1 Cdr, Det A, 55th PSB, (Attn: Records Section), APO AE 09165
- 2 SJA, V Corps, APO AE 09014
- 1 Record Set
- 1 Reference Set
- 1 Cdr, Hqs Det, 39th Finance Battalion, APO AE 09165
- 1 Cdr, USAEREC, ATTN: PCRE-FS, Fort Benjamin Harrison, IN 46249
- 10 Clerk of Court (JALS-CC), Nassif Bldg, Falls Church, VA 22041-5013

VERBATIM :

#### RECORD OF TRIAL

(and accompanying papers)

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I IIND Jeremy 1

(Name: Last, First, Middle Initial)

Co A. 127th Avn Snt Bn

(Unit/Command Name)

United States Army (Branch of Service)

APO AF OUISE (Station or Ship)

В٧

GENERAL

COURT-MARTIAL

Convened by

THE COMMANDER

(Title of Convening Authority)

CORPS

(Unit/Command of Convening Authority)

Tried at

Mannheim & Hanau,

Federal Republic of Germany (Place or Places of Trial)

16 & 30 December, 1998

(Date or Dates of Trial)

**ALLIED PAPERS** 

COMPANION CASES:

PVT Kurtis Armann, SPC Roy P. Tarbox.

ny9900316-CMCR my 9900180-A3>

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ise ", "verbatim" or summarized" as appropriate. (This form will be used by the Army, and Navy for verbatim records of trial only )

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Front Cover

VOL I OF III

#### DEPARTMENT OF THE ARMY Headquarters V Corps APO AE 09014

GENERAL COURT-MARTIAL ORDER NUMBER 23

25 May 1999

U.S. Army, A Company, 127th Aviation Support Battalion, SPC Jeremy J. Lund, APO AE 09165, was arraigned at Mannheim, Germany, on the following offenses at a general court-martial convened by Commander V Corps.

Charge I. Article 80. Plea: Guilty. Finding: Guilty.

The Specification. Attempted premeditated murder with a firearm, at Hanau, Germany, on or about 10 October 1998. Plea: Guilty. Finding: Guilty.

Charge II. Article 81. Plea: Guilty. Finding: Guilty.

The Specification. Conspiracy to commit premeditated murder, at Hanau, Germany, between on or about 1 March 1998 and on or about 10 October 1998. Plea: Guilty. Finding: Guilty.

#### SENTENCE

Sentence was adjudged on 14 January 1999. To be reduced to the grade of E1, to forfeit all pay and allowances, to be confined for 25 years, and to be discharged from the service with a dishonorable discharge.

#### ACTION

Only so much of the sentence as provides for reduction to the grade of E1, forfeiture of all pay and allowances, confinement for 14 years, and a dishonorable discharge is approved and, except for the part of the sentence extending to a dishonorable discharge, will be executed.

BY COMMAND OF LIEUTENANT GENERAL HENDRIX:

DISTRIBUTION:

1 Each Individ concern

1 COL Peter E. Brownback III (MJ)

1 CPT Carlene Christie (TC)

1 MAJ Craig Meredith (ATC)

LTC, JA

Chief, Criminal Law Division

#### GCMO No 23, HQ V Corps, APO AE 09014, dated 25 May 1999

- 1 MAJ Steven Brodsky (DC)
- 1 CPT Richard Raleigh Jr. (ADC)
- 1 Cdr, 127th AVN SPT BN, APO AE 09165
- 1 Cdr, Det A, 55th PSB, (Attn: Records Section), APO AE 09165
- 2 SJA, V Corps, APO AE 09014
- 1 Record Set
- 1 Reference Set
- 1 Cdr, HQ Det 39th Finance Battalion, APO AE 09165
- 1 Cdr, USAEREC, ATTN: PCRE-FS, Fort Benjamin Harrison, IN 46249
- 10 Clerk of Court (JALS-CC), Nassif Bldg, Falls Church, VA 22041-5013

Copy 1 Volume 1 of 1

#### **VERBATIM**

#### RECORD TRIAI OF

(and accompanying papers)

Of

OIE. Monica S. (Name: Last, First, Middle Initial)

(Social Security Number)

Private E1

(Rank)

B Company, 127th Aviation Support Battallon, US Army, APO AE 09165

(Unit/Command Name)

(Branch of Service)

(Station or Ship)

By

#### GENERAL COURT-MARTIAL

Convened by THE COMMANDER

(Title of Convening Authority)

CORPS

(Command of Convening Authority)

Tried At

Hanau,

Federal Republic of Germany

(Place or Places of Trial)

On

26 April and 4 May 1999

(Date or Dates of Trial)

COMPANION CASES:

TARBOX, Roy P., ARMY 9900 180 LUND, Jeremy J. ATMY 9900 116

A Co, 127th ASB, US Army APO AE 09165

APO AE 09165

ROESELER. David M. ARINY SPC,

A Co, 127th ASB, US Army (CO)

APO AE 09165

- OIE, Manica Sa PVT,

B Co, 127th ASB, US Army AFO AE 09165

GIBSON, Scott: DIALWAY 99 DOST 5

B Co, 127th ASB, US Army

ARMANN, Kurtis E. Army 99003, 6 PVT, A Co, 127th ASB, US Army CMCR

APO AE 09165

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Front Cover

## DEPARTMENT OF THE ARMY Headquarters V Corps APO AE 09014

GENERAL COURT-MARTIAL ORDER NUMBER 28

8 July 1999

Private Monica S. Oie, S. Army, B. Company, 127th Aviation Support Battalion, APO AE 09165, was arraigned at Hanau, Germany; on the following offenses at a general court-martial convened by Commander V Corps.

Charge I. Article 81. Plea: Guilty. Finding: Guilty.

The Specification: Conspiracy to commit premeditated murder, at or near Erlensee, Germany, between on or about 1 February 1998 and 10 October 1998. Pleas Guilty. Finding: Guilty.

Charge II. Article 92. Plea: Guilty. Finding: Dismissed.

The Specification: Violate a lawful general regulation by wrongfully possessing drug abuse paraphernalia, at or near Erlensee, Germany, on or about 1 February 1999. Plea: Guilty. Finding: Dismissed.

Charge III [renumbered as Charge II]. Article 107. Plea: Guilty. Finding: Guilty.

The Specification: Render false statements, at or near Hanau, Germany, on or about 11 October 1998. Plea: Guilty. Finding: Guilty.

Charge IV [renumbered as Charge III]. Article 112a. Plea: Guilty. Finding: Guilty.

Specification 1: Wrongfully used marijuana, at or near Erlensee, Germany, on or about 11 October 1998. Plea: Guilty. Finding: Guilty.

Specification 2: Wrongfully used and possessed marijuana, at or near Erlensee, Germany, on or about 1 February 1999. Plea: Guilty. Finding: Guilty.

Charge V [renumbered as Charge IV]. Article 134. Plea: Guilty. Finding: Guilty.

Specification: Wrongfully solicit PVT Kurtis E. Armann and SPC David M. Roeseler to commit murder, at or near Erlensee, Germany, between on or about 1 February 1998 and 10 October 1998. Plea: Guilty. Finding: Guilty.

GCMO No 28, HQ V Corps, APO AE 09014, dated 8 July 1999

#### SENTENCE

Sentence was adjudged on 4 May 1999. To forfeit all pay and allowances, to be dishonorably discharged from the United States Army, and to be confined for a period of ten (10) years.

#### ACTION

Only so much of the sentence as provides for forfeiture of all pay and allowances, confinement for two years, and a dishonorable discharge is approved and, except for the part of the sentence extending to a dishonorable discharge, will be executed.

SFC, USA

NCOIC, Criminal Law Division

BY COMMAND OF LIEUTENANT GENERAL HENDRIX:

DISTRIBUTION:

1 Each Individ concern

1 COL Brownback III (MJ)

1 CPT Christie (TC)

1 CPT Grason (DC)

1 Cdr, B Co, 127th Avn Sup Bn, APO AE 09165

1 Cdr, Det A, 55th PSB, (Attn: Records Section), APO AE 09175

2 SJA, V Corps, APO AE 09014

1 Record Set, 1 Reference Set

1 Cdr, HQ Det, 39th Finance Battalion, APO AE 09175

1 Cdr, USAEREC, ATTN: PCRE-FS, Fort Benjamin Harrison, IN 46249

10 Clerk of Court (JALS-CC), Nassif Bldg, Falls Church, VA 22041-5013

Copy 1 Volume \_L of \_!!

#### VERBATIM

#### RECORD TRIAL

(and accompanying papers)

Of

GIBSON, Scott D.

(Name: Last, First, Middle Initial)



Private E1

(Rank)

B Company, 127th Aviation Support Battalion, US Army, APO AE 09165

(Unit/Command Name)

(Branch of Service)

(Station or Ship)

By

#### GENERAL COURT-MARTIAL

Convened by THE COMMANDER

(Title of Convening Authority)

CORPS

(Command of Convening Authority)

Tried At

Hanau and Mannheim, Federal Republic of Germany

(Place or Places of Trial)

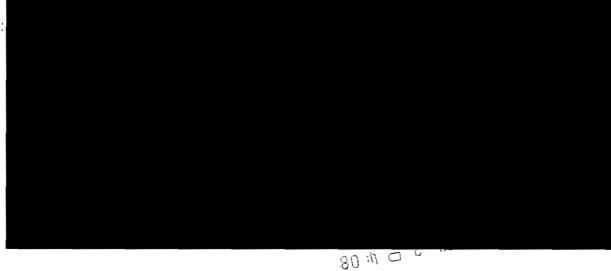
On

26 April, 6 May, 14 May and

1. 2 & 3 June 1999

(Date or Dates of Trial)

COMPANION CASES:



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CLERK OF COURT Copy 1 Volume L of III

#### DEPARTMENT OF THE ARMY Headquarters, V Corps APO AE 09014

GENERAL	COURT-MARTIAL	ORDER
NUMBER		41

3 October 1999

PVT Scott D. Gibson, U.S. Army, B Company, 127th Aviation Support Battalion, APO AE 09165, was arraigned at Hanau, Germany, on the following offenses at a general court martial convened by Commander, V Corps.

Charge I. Article 81. Plea: Not Guilty. Finding: Guilty.

The Specification: Conspiracy to commit premeditated murder, at or near Hanau, Germany, between on or about 1 July 1998 and on or about 10 October 1998. Plea: Not Guilty. Finding: Guilty, except the words, "the said Private Gibson and Private Armann did reconnoiter trails adjacent to PFC Bell's quarters, at or near Pioneer Kaserne, Hanau, Germany, for the purpose of determining the best method of shooting PFC Bell while she walked her dog." Of the excepted words: Not Guilty.

Charge II. Article 92. Plea: Not Guilty. Finding: Guilty.

The Specification: Violation of lawful general regulation by wrongfully using and possessing drug abuse paraphernalia, at or near Erlensee, Germany, on or about 1 February 1999. Plea: Not Guilty. Finding: Guilty.

Charge III. Article 107. Plea: Not Guilty. Finding: Guilty.

The Specification: False official statement, at or near Hanau, Germany, on or about 11 October 1998. Plea: Not Guilty. Finding: Guilty.

Charge IV. Article 112a. Plea: Not Guilty. Finding: Guilty.

The Specification: Possession and use of marijuana, at or near Erlensee, Germany, on or about 1 February 1999. Plea: Not Guilty. Finding: Guilty.

#### SENTENCE

Sentence was adjudged on 3 June 1999. To total forfeiture of all pay and allowances, to be confined for a period of five years, and to be dishonorably discharged from the Army.

GCMO No 41, HQ, V Corps, APO AE 09014, dated 8 October 1999

#### ACTION

SFC, USA

NCOIC, Criminal Law Division

The sentence is approved and, except for the part of the sentence extending to a dishonorable discharge, will be executed.

BY COMMAND OF LIEUTENANT GENERAL HENDRIX:

#### DISTRIBUTION:

- 1 Each Individ concern
- 1 COL Peter E. Brownback III (MJ)
- 1 CPT Krista K. Bush (TC)
- 1 CPT Jonathan Howard (DC)
- 1 Cdr, B Company, 12.7th Aviation Battalion, APO AE 09165
- 1 Cdr, Det A, 55th PSB, (Attn: Records Section), APO AE 09165
- 2 SJA, V Corps, APO AE 09014
- 1 Record Set
- 1 Reference Set
- 1 Cdr, HQ Det, 39th Finance Battalion, APO AE 09165
- 1 Cdr, USAEREC, ATTN: PCRE-FS, Fort Benjamin Harrison, IN 46249
- 10 Clerk of Court (JALS-CC), Nassif Bldg, Falls Church, VA 22041-5013

#### CERTIFICATE OF SERVICE

UNITED STA	TES v.	beman	\$L_

ASSIGNMENT OF ERROR

MOTION

I certify that a copy of the foregoing was delivered to the Government Appellate Division on 14

Paralegal Specialist

Defense Appellate Division

U.S. Army Legal Services Agency

#### INSTRUCTIONS FOR PREPARING AND ARRANGING RECORD OF TRIAL

USE OF FORM - This form and MCM, 1984, Appendix 14, will be used by the trial counsel and the reporter as a guide to the preparation of the record of trial in general and special court-martial cases in which a verbatim record is prepared. Air force uses this form and departmental instructions as a guide to the preparation of the record of trial in general and special court-martial cases in which a summarized record is authorized. Army and Navy use DD form 491 for records of trial in general and special court-martial cases in which a summarized record is authorized. Inapplicable words of the printed text will be deleted.

COPIES - See MCM, 1984, RCM 1103(g) The convening authority may direct the preparation of additional copies.

ARRANGEMENT - When forwarded to the appropriate Judge Advocate General or for judge advocate review pursuant to Article 64(a), the record will be arranged and bound with allied papers in the sequence indicated below. Trial counsel is responsible for arranging the record as indicated, except that items 6, 7, and 15e will be inserted by the convening or reviewing authority, as appropriate, and items 10 and 14 will be inserted by either trial counsel or the convening or reviewing authority, whichever has custody of them

- 1. Front cover and inside front cover (chronology sheet) of DD form 490.
- 2 Judge advocate's review pursuant to Article 64(a), if any.
- 3 Request of accused for appellate defense counsel, or waiver/withdrawal of appellate rights, if applicable.
- 4. Briefs of counsel submitted after trial, if any (Article 38(c)).
  - 5 DD Form 494, "Court-Martial Data Sheet."
- 6 Court-martial orders promulgating the result of trial as to each accused, in 10 copies when the record is verbatim and in 4 copies when it is summarized.
- 7 When required, signed recommendation of staff judge advocate or legal officer, in duplicate, together with all clemency papers, including clemency recommendations by court members

- 8. Matters submitted by the accused pursuant to Article 60 (MCM, 1984, RCM 1105).
- 9. DD Form 458, "Charge Sheet" (unless included at the point of arraignment in the record).
  - 10. Congressional inquiries and replies, if any
- 11. DD Form 457, "Investigating Officer's Report," pursuant to Article 32, if such investigation was conducted, followed by any other papers which accompanied the charges when referred for trial, unless included in the record of trial proper.
- 12. Advice of staff judge advocate or legal officer, when prepared pursuant to Article 34 or otherwise
- 13. Requests by counsel and action of the convening authority taken thereon (e.g., requests concerning delay, witnesses and depositions).
  - 14 Records of former trials
  - 15. Record of trial in the following order:
    - a Errata sheet, if any
- b Index sheet with reverse side containing receipt of accused or defense counsel for copy of record or certificate in lieu of receipt
- c Record of proceedings in court, including Article 39(a) sessions, if any
- d Authentication sheet, followed by certificate of correction, if any
- e Action of convening authority and, if appropriate, action of officer exercising general court-martial jursidiction.
  - f. Exhibits admitted in evidence
- g Exhibits not received in evidence. The page of the record of trial where each exhibit was offered and rejected will be noted on the front of each exhibit.
- h. Appellate exhibits, such as proposed instructions, written offers of proof or preliminary evidence (real or documentary), and briefs of counsel submitted at trial